EXHIBIT F

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO WAVE 1**	**Master File No. 2:12-MD-02327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RULE 26 EXPERT REPORT OF DUANE PRIDDY, PH.D.

I. QUALIFICATIONS

In 1971 I received a Ph.D. in Organic Chemistry from Michigan State University. I joined Dow Plastics in 1972. I retired from Dow Plastics in 2001 as a Principal Scientist. During my years at Dow, I led a team of Plastic Scientists that worked together to understand the science of plastic degradation in order to help Dow develop improved antioxidant stabilizer formulations for Dow's plastic products. Our goal was to understand, not only the mechanism of degradation of plastics, but also the mechanism of degradation of antioxidants causing them to become depleted from the plastic. In 1995 I published a peer reviewed scientific paper entitled "Permanence of Polymer Stabilizers in Hostile Environments," which addresses the topic of the loss of stabilizers from plastics allowing the plastic to rapidly degrade.[1] I also helped Dow develop several medical grade plastic formulations. Following my retirement from Dow in 2001, I started Plastic Failure Labs. Over the past decade I have served as an expert witness in over 150 litigations involving the failure of plastic products, including medical devices. I have published many articles and scientific publications involving the science of plastics, how they fail, and how to select the right plastic for specific applications.

Because of my many contributions to the development of a better understanding of the science of degradation of plastics, I have received many awards and honors including: Lifetime Achievement Award (Dow), Fellow (Polymeric Materials Div. of the American Chemical Society), and Fellow (Society of Plastic Engineers). I have worked as a plastics consultant for the following medical supply companies: Spectranetics, StatLabs, Baxa, Terumo, and American Medical Systems performing failure analysis, material selection, and product life predictions. A full and accurate copy of my Curriculum Vitae is attached as Exhibit A.

[1] "Permanence of polymer stabilizers in hostile environments," Journal of Applied Polymer Science (1994), 54(11), 1605-12.

II. EXECUTIVE SUMMARY

I have been asked to address the chemical stability of the polypropylene (PP) polymer used by Ethicon, Inc., Gynecare, and Johnson & Johnson (collectively referred to as Ethicon) associated with the manufacture of Ethicon's mesh products designed to treat Stress Urinary Incontinence (SUI) and Pelvic Organ Prolapse (POP). When I refer to PP in this Report, I am referring to the PP resin used by Ethicon in both their SUI and POP devices. All of my opinions in this Report are offered to a reasonable degree of professional certainty within my field.

There are thousands of different plastic products and grades on the market. Choosing the right plastic for any given application is critical, especially for medical implants where failure can be life-threatening. As a Plastic Scientist, I have been trained and have devoted my 40+ year career developing a scientific understanding of how different plastics perform under different use conditions, including for medical applications. I have also developed an understanding of the degradation science of different plastics, their service life, and how they eventually fail. Based on my education, training and experience, my opinion in this case is that Ethicon should not have used PP in its SUI and POP devices because of the unstable chemical nature of this material. The testing and analysis that I have done as part of my work confirms my opinions based on the scientific literature and my experience. Furthermore, the testing that I have done in this case is the same testing and analysis that I have done throughout my career, including as part of my work for Dow Plastics and is accepted by my peers and industry. I would have performed this same analysis and testing for Ethicon at any time during the marketing of their SUI and POP PP devices if they had asked me to do so and would have given them the same opinions I set forth in this report.

Because of the reactive tertiary carbon—hydrogen bonds along the PP polymer chains—PP is not inert[2] and must be heavily stabilized with the addition of antioxidants in order to simply survive fabrication into parts. The addition of antioxidants to PP allows it to be fabricated into parts and prolongs its useful life. However, it is not possible or feasible to stabilize PP to make it last for decades in an application where it:

1) has high surface area exposed to oxygenated medium;
2) is under stress;
3) is in a constant warm environment; and
4) is exposed to fluids containing organics capable of extracting antioxidant stabilizers from the exposed surface.

These basic Polymer Science principles are accepted in my field of expertise. Accordingly, it is my opinion that Ethicon should not have used PP as a material in permanent medical implants.

As part of my work in this case, I have performed ASTM D3895 "Oxidative Induction Time" (OIT) testing. ASTM 3895 OIT is a standard test method that outlines a procedure for determining the resistance of a material to oxidation using differential scanning calorimetry (DSC). This testing is

[2] *See* E. Rene de la Rie. *Polymer Stabilizers. A Survey with Reference to Possible Applications in the Conservation Field*. STUDIES IN CONSERVATION. 33: 9-22 (1988); Clavé, A. et al. *Polypropylene as a Reinforcement in Pelvic Surgery is not Inert: Comparative Analysis of 100 Explants.* Int. Urogynecol. J. 21:261-270 (2010); Costello, C.R. et al. *Materials Characterization of Explanted Polypropylene Hernia Meshes.* J. Biomed Mater. Res. Part B: Appl. Biomaterials. 83B: 44-49 (2007).

an accelerated thermal aging test which is commonly used to evaluate the oxidative resistance of polyolefin resins like PP.[3,4] OIT measures a material's resistance to oxidative decomposition. As part of my work in this case, OIT was used to compare the relative thermal oxidative stability of 10 different Ethicon mesh samples in order to determine the lot to lot variability of the oxidative stability of the meshes. As part of my work in this case, I followed a standardized protocol listed in ASTM D3895. I did not deviate from the protocol listed in this testing procedure. I examined the data to also determine the point at which the surface of the mesh shows evidence of incipient oxidation. This measures incipient surface oxidation time (ISOT), which is measuring surface oxidation. Measuring surface oxidation is important because how and when oxidation affects the surface of PP is the beginning of the embrittlement process, which will affect the physical structure of the PP.

Over 150% variance was found between the 10 exemplar samples. This variance is significant because it indicates that there are wide differences among the oxidative stability of the ten (10) tested samples. These differences between different samples indicates that the oxidation process will be unpredictable—meaning that the material in different lots of Ethicon SUI and POP PP devices will degrade at varying rates. Thus the products are not expected to behave consistently across product lines and within product lines.

The data was also used to evaluate the performance of the antioxidant stabilizer in the Ethicon mesh samples and to predict the approximate time to oxidative degradation of the meshes following the Q10 protocol[5] as described in ASTM F1980 accelerated aging testing methodology. The estimated time for depletion of the antioxidants to measure incipient surface oxidative degradation of the meshes (under best case scenario conditions; i.e., no stress and no loss by extraction) is only a few months in some of the mesh samples. This result provides additional support for my opinion in this case that PP should not be used as a permanently implantable medical material due to its unstable chemical nature; that the oxidative process begins quickly; and that the oxidative process is accelerated in an environment of stress, heat and oxidative agents. This is well-documented in the scientific literature and it is commonly understood in my field. There is nothing unique about the Ethicon PP that changes these fundamental principles of polymer science.

Because the degradation science of PP has been well known for over 40 years,[6] and the availability of accelerated laboratory aging technology allowing rapid assessment of the rate of material degradation,[7] it is clear that Ethicon meshes manufactured using PP cannot survive long

[3] Antioxidant Depletion and OIT Values of High Impact PP Strands"; Chinese Journal of Polymer Science , 27(3), 435−445(2009).

[4] "Accelerated testing method for evaluating polyolefin stability", ASTM special technical Publication: 1081", edited by Koerner, R.M., ASTM, page 57 (1990).

[5] "Shelf-Life Prediction for Radiation-Sterilized Plastic Devices," Medical Device Diagnostics,12(1):124–129 (1990); "How to Plan an Accelerated Life Test—Some Practical Guidelines", 10, Milwaukee, WI, American Society for Quality Control, 1985; "Shelf-Life Prediction of Radiation Sterilized Medical Devices," Society of Plastics Engineers ANTEC Technical Papers, 33, (1987); "Using the Arrhenius Equation and Rate Expressions to Predict the Long-Term Behavior of Geosynthetic Polymers," Geosynthetics, (1993); "Standard Practice for Heat Aging of Plastics without Load," ASTM Report D3045, West Conshohocken, PA, ASTM; Woo L, and Cheung W, "Importance of Physical Aging on Medical Device Design," Society of Plastics Engineers ANTEC Technical Papers, 34 (1988); http://www.met.uk.com/medical-device-packaging-testing/4a-medical-accelerated-ageing.php .

[6] "The Deterioration of PP by Oxidative Degradation"; Polymer Engineering & Science, 152 (1965).

[7] "Shelf-Life Prediction for Radiation-Sterilized Plastic Devices," Medical Device Diagnostics,12(1):124–129 (1990); "How to Plan an Accelerated Life Test—Some Practical Guidelines", 10, Milwaukee, WI, American Society

term use as a reinforcing medical implant. Ethicon knew, or should have known; that this process of degradation affects the plastic's integrity from the beginning and can be predicted. PP's chemical nature and resulting instability also means that the Ethicon PP may degrade more rapidly based on the environment that it is in.

III. EXPLANATION OF PLASTIC STRENGTH

The longer the polymer chains, the greater the number of polymer chain entanglements, and the stronger the plastic. The general rule for plastics is that there should be at least an average of ten entanglements of each polymer chain with the other polymer chains for the plastic to have good strength. When plastics oxidize, the chains are broken and become shorter resulting in fewer entanglements and eventually the normally strong/ductile plastic becomes brittle like glass. This oxidation process starts before implant, as PP is subject to degradation or weakening by oxidative agents, including those found in the human body.[8]

IV. BACKGROUND ON OXIDATION AND DEGRATION OF HYDROCARBON MATERIALS

Hundreds of billions of pounds of plastic materials are manufactured and used each year around the world. Plastics are inherently oxidizable because they are hydrocarbons; i.e., they contain hydrogen bonded to carbon. Oxygen in the air oxidizes hydrocarbon materials replacing the hydrogen with oxygen causing them to degrade.[9] This is true of all materials that contain hydrogen bonded to carbon including the food we eat and the medicines we take. This is why the food we buy at the store and the medicines we take all have expiration dates on them. Because of the fact that most plastics are inherently unstable and degrade by oxidation, antioxidant stabilizers are generally added to plastics during their manufacture. These antioxidants allow the plastic to be heated and fabricated into parts and also prolong the useful life of the plastic. However, eventually the antioxidant stabilizers are consumed, allowing the plastic to oxidize and degrade. Some plastics are less stable and oxidize and degrade much faster than other plastics; e.g., PP. PP is a cheap commodity plastic. Because of its poor oxidative stability, PP is generally used primarily to manufacture products that have a short service life.

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for Quality Control, 1985; "Shelf-Life Prediction of Radiation Sterilized Medical Devices," Society of Plastics Engineers ANTEC Technical Papers, 33, (1987); "Using the Arrhenius Equation and Rate Expressions to Predict the Long-Term Behavior of Geosynthetic Polymers," Geosynthetics, (1993); "Standard Practice for Heat Aging of Plastics without Load," ASTM Report D3045, West Conshohocken, PA, ASTM; Woo L, and Cheung W, "Importance of Physical Aging on Medical Device Design," Society of Plastics Engineers ANTEC Technical Papers, 34 (1988); http://www.met.uk.com/medical-device-packaging-testing/4a-medical-accelerated-ageing.php .

[8] *See* E. Rene de la Rie. *Polymer Stabilizers. A Survey with Reference to Possible Applications in the Conservation Field*. STUDIES IN CONSERVATION. 33: 9-22 (1988); Clavé, A. et al. *Polypropylene as a Reinforcement in Pelvic Surgery is not Inert: Comparative Analysis of 100 Explants.* Int. Urogynecol. J. 21:261-270 (2010); Costello, C.R. et al. *Materials Characterization of Explanted Polypropylene Hernia Meshes.* J. Biomed Mater. Res. Part B: Appl. Biomaterials. 83B: 44-49 (2007).

[9] "What is oxidation and how does it alter food products?", http://shelflifeadvice.com/faq/what-oxidation-and-how-does-it-alter-food-products

Basic principles of chemistry teach that hydrocarbons (chemicals that contain hydrogen bonded to carbon) are constantly degrading by oxidation (reaction with oxygen).[10] When a material containing hydrogen bonded to carbon (C---H) is exposed to air, the hydrogen becomes replaced with oxygen by a free radical process. The rate of the oxidation reaction is about 10 times faster when the hydrogen is bonded to a tertiary carbon (as in PP) compared to a secondary carbon (as in polyethylene). For example, this is why PP degrades (by oxidation) much faster than polyethylene.[11] Because of the poor oxidation resistance of PP, PP must be heavily stabilized with antioxidants in order for the material to survive fabrication into articles and for the fabricated articles to have a reasonable service life. As a plastic chemist, I am aware that additives in plastics can migrate and are extractible, that antioxidant stabilizers added to medical implants must be suitable for use in medical devices, and that the antioxidants cannot be toxic to adjacent tissue surrounding the implant.

Based on my education, training and experience, I would not recommend the use of PP mesh as an implantable medical device, especially if that device cannot be removed in its entirety if complications arise. Degradation does not stop and the chemical reactions continue to occur so long as any oxidizing agents, such as those present in the human body, are present.[12] This means the oxidative process does not stop in the body until all of the mesh is removed.

V. PLASTICS IN MEDICINE

A. General

Plastics, including PP, are extensively used in medicine. Examples include pill bottles, petri dishes and tubing. However, these applications are short term and are external to the body so failure is not generally life-threatening. When plastics are placed in the body, the environment in is very different than outside the body. For example, when plastics are placed in the body, they are exposed to organic liquids (e.g., blood and fatty oils called lipids, glycerides). These chemicals act to extract the antioxidant stabilizers (very small molecules) from the long polymer chains in the plastic. Implantation of plastic inside the body also places a mechanical load or stress on it. In response to the mechanical stress, the polymer chains start to disentangle from each other and the plastic becomes weaker over time, eventually becoming brittle. As an implanted material loses its strength and fails, it can be a safety issue which can lead to serious infection and the need for further surgery. The oxidative process itself results in changes to the material, which can lead to embrittlement and complete oxidation. As I also note above, these chemical reactions can also be problematic if the PP cannot be removed.

B. Plastic Implants

[10] "Aerobic hydrocarbon oxidation," https://www.boundless.com/microbiology/textbooks/boundless-microbiology-textbook/microbial-metabolism-5/alternatives-to-glycolysis-47/aerobic-hydrocarbon-oxidation-303-3442/
[11] Biodegradation of Polypropylene and Polyethylene"; Indian Journal of Biotechnology, 7, 9 – 22 (2008).
[12] Anderson, J.M., et al. *Foreign Boyd Reaction to Biomaterials*. Semin. Immulon. 20(2): 86-100 (2008).

One of the success stories of implanted plastics is artificial joints.[13] Because artificial joints are under very high mechanical stress during use, in order to overcome the problem with polymer chain disentanglement, manufactures of artificial joints make the polymer chains extremely long to maximize the number of entanglements. The polymer chains are so entangled that when some disentanglement occurs, they will always have greater than the minimum of ten entanglements required for good strength. The plastic material of choice for artificial joints is called ultra-high molecular weight polyethylene or UHMWPE.

A big challenge with UHMWPE is that the polymer chains are so long and so entangled that the plastic is extremely difficult to mold into shapes, thereby necessitating the use of special molding techniques.[14] As mentioned previously, polyethylene does not contain tertiary carbon – hydrogen bonds so it is much more stable than PP. However, even though UHMWPE has ultra-long polymer chain length and has much greater oxidative stability than PP, it still eventually degrades by oxidation often forcing replacement of the artificial joints after several years of service.[15] This is well known to me in my work because I have worked with and tested these concepts throughout my professional career. The testing I have performed as part of my work in this case is the same testing that I have used throughout my career, including with medical devices, and this testing is widely accepted in my field.

VI. MESH

A. Loss of strength by Polymer Chain Disentanglement

PP is the plastic used in the Ethicon mesh/fabric.[16] The mesh/fabric consists of threads that are woven together. In order to be able to extrude the PP to make skinny thread, the PP chains cannot be extremely long like those in the UHMWPE used for artificial joints because it would be impossible to force the extremely long polymer chains through a small die-opening to make skinny thread. Since the polymer chains are short and PP is prone to oxidative degradation, exposure of the mesh to stress in the body can cause the mesh to fail. Since the rate of oxidation and antioxidant extraction is greatest on the surface of the mesh fibers, the surface rapidly degrades and becomes brittle.[17] This basic scientific principle is well known and has been understood for several decades. Therefore a Plastic Scientist with an understanding of the degradation science of plastics can predict that PP mesh implants can begin to oxidize and degrade after implantation.

B. Loss of Strength by Oxidation

The basic chemistry of the oxidation of PP is depicted below:

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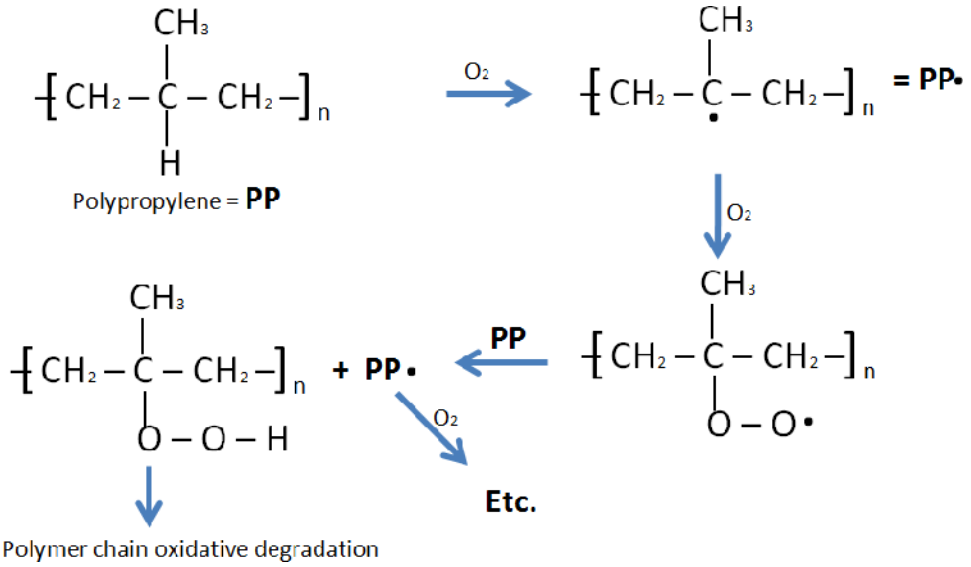
[13] "UHMWPE: Processing and Problems", www.uhmwpe.unito.it/2003/Allen.pdf; "UHMWPE Biomaterials handbook", https://books.google.com/books?hl=en&lr=&id=-50t0rdc0BgC&oi=fnd&pg=PP1&dq=molding+of+UHMWPE&ots=_KrkrTgRBX&sig=zX7hJUHNa12wqte-OMpxIeRA8Rw#v=onepage&q=molding%20of%20UHMWPE&f=false

[14] "UHMWPE: Processing and Problems", www.uhmwpe.unito.it/2003/Allen.pdf

[15] "UHMWPE Biomaterials handbook", https://books.google.com/books?hl=en&lr=&id=-50t0rdc0BgC&oi=fnd&pg=PP1&dq=molding+of+UHMWPE&ots=_KrkrTgRBX&sig=zX7hJUHNa12wqte-OMpxIeRA8Rw#v=onepage&q=molding%20of%20UHMWPE&f=false

[16] *See* Eth.Mesh.02268619 ("Prolene Resin Manufacturing Specifications").

[17] "Subcutaneous Implants of PP Filaments"; Journal of Biomedical Material Research, 10, 939 – 851 (1976).



Oxygen in the air abstracts the labile (reactive) tertiary hydrogen (H) atoms from the PP backbone to produce carbon free radicals. Carbon free radicals are highly reactive and rapidly react with oxygen to form peroxide radicals. Peroxide radicals are also highly reactive and react with other tertiary H atoms on PP to form more PP radicals and convert the peroxy radical to a hydroperoxide group which is unstable and decomposes to form a ketone causing the PP polymer chain to break into two shorter chains and to propagate a chain reaction. If PP is not stabilized with antioxidants, it will be so unstable that it would not even survive being heated up and fabricated to make a mesh, let alone survive implantation into a highly oxidizing environment inside the body. The only thing that allows Ethicon mesh to survive even short term implantation is the presence of antioxidants (e.g., Santanox R) which interfere with the oxidative chain reaction.

However, there are inherent problems with implanting an unstable plastic in the body and relying on antioxidants to prolong its life. The problems include: reliance upon small molecules which migrate from the surface of the mesh;[18] and the antioxidants are themselves degraded over time[19] becoming depleted from the PP. Once the antioxidants are extracted by body fluids and depleted from the surface of the mesh, surface embrittlement of the fibers ensues (Figure 1). Embrittlement of the PP occurs on the surface and leads to microcracking, which then stimulates crack initiation and crack propagation. If mechanical stress is also placed on the PP fibers, it will enhance the degradation effect and further lead to crack propagation, especially with a material that is under a constant mechanical stress. Embrittlement of the surface of the PP mesh fibers leads to a substantial decrease in the mechanical and physical properties of meshes. This is basic polymer chemistry that is well understood by Plastic Scientists and was known at the time that Ethicon began using PP in SUI and POP products.[20]

[18] "Loss of stability by migration and chemical reaction of Santonox R..."; Polymer Degradation and Stability 91, 1071-1078 (2006).
[19] "Permanence of polymer stabilizers in hostile environments," Journal of Applied Polymer Science (1994), 54(11), 1605-12.
[20] "Characterization and Failure Analysis of Plastics," ASM International (2003), https://books.google.com/books?id=RJWiilJLdxYC&pg=PA17&lpg=PA17&dq=affect+of+polymer+molecular+wei

VII. SANTANOX R ANTIOXIDANT USED IN ETHICON MESH

The PP used in Ethicon mesh is stabilized using antioxidants (e.g., Santanox R).[21] Ethicon documentation reveals that there are additional additives added to the Prolene resin, including Calcium Stearate, Dilauralthiodipropionate (DLTDP), Procol LA-10, and CPC Pigment.[22] My testing in this case (gas chromatography – mass spectroscopy (GC-MS)) did not detect the presence of any of the additive other than Santanox R.

The chemical oxidation process of plastics and the stabilization chemistry of antioxidants like Santanox R are well understood (Scheme 1). Santanox R contains both hindered phenol and sulfur. Sulfur reacts with peroxides to convert them to alcohols. A problem is, as the Santanox R does its job, it is constantly being converted to a different chemical which is not an antioxidant. It is also known that Santanox R is depleted by migration into adjacent fluid.[23] Once depleted, the PP is completely unstabilized and is free to more rapidly oxidize and become brittle. Of course, the degradation process occurs first on the surface of the fibers because of the migration of the antioxidants from the surface, and the oxidizing environment is greatest on the fiber surface. This is why the scientific literature shows embrittlement of the surface layer on the fibers of explanted meshes (Figure 1).[24]

Scheme 1. The chemistry of PP oxidation stabilized with Santanox R.

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ght+on+the+mechanical+strength+of+plastics&source=bl&ots=L2PXkQGtcM&sig=4HhsQEiRxWqz_bGzRP6vuIgzBnY&hl=en&sa=X&ved=0ahUKEwjD27f7-cDKAhXrw4MKHeIlAF0Q6AEIMjAD#v=onepage&q=affect%20of%20polymer%20molecular%20weight%20on%20the%20mechanical%20strength%20of%20plastics&f=false

[21] *See* Eth.Mesh.02268619 ("Prolene Resin Manufacturing Specifications").

[22] Id.

[23] "Loss of stability by migration and chemical reaction of Santonox R..."; Polymer Degradation and Stability 91, 1071-1078 (2006).

[24] Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants"; Int Urogynecol Journal, 21, 261–270 (2010); Biodegradation of Surgical Polymers"; Journal of Material Science, 17, 1233 – 46 (1982); Materials Characterization of Explanted Polypropylene Hernia Meshes"; Journal of Biomechanical Materials Research, Part B: Applied Biomaterials, 83B: 44–49 (2007); Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients"; Journal Biomed Mater Res Part B: Applied Biomaterials 91B: 1 - 12, (2015); "In vivo Oxidative Degradation of Polypropylene Pelvic Mesh"; Biomaterials, 71, 131 – 141 (2015); "Materials characterization and histological analysis of explanted PP, PTFE, and PET hernia meshes from an individual patient"; Journal of Material Science: Material Medicine; 24, 1113 – 1122 (2013); Mesh Sling in an Era of Uncertainty: Lessons Learned and the Way Forward"; European Urology, 64, 525 – 529 (2013); Modified classification of surgical meshes for hernia repair based on the analyses of 1,000 explanted meshes"; Hernia, 16, 251 – 258 (2012); "Pathological Findings of Transvaginal PPP Slings Explanted for Late Complications: Mesh is not Inert"; Conference paper presented in 2014; see https://www.researchgate.net/publication/273135551PathologicalFindingsofTransvaginalPolypropyleneSlingsexplantedforLateComplicationsMeshisNotInert; "Failure Analysis of Transvaginal Mesh Products a Biomaterials Perspective Using Materials Science Fundamentals"; Paper presented at 2014 AICHE conference; "Pathology of Explanted Transvaginal Meshes"; International Journal of Medical Health, 8(9), 510 – 513 (2014); "Physical Characteristics of Medical Textile Prostheses Designed for Hernia Repair: A Comprehensive Analysis of Select Commercial Devices"; Materials, 8(12), 8148-8168 (2015); Biodegradation of Polypropylene and Polyethylene"; Indian Journal of Biotechnology, 7, 9 – 22 (2008).

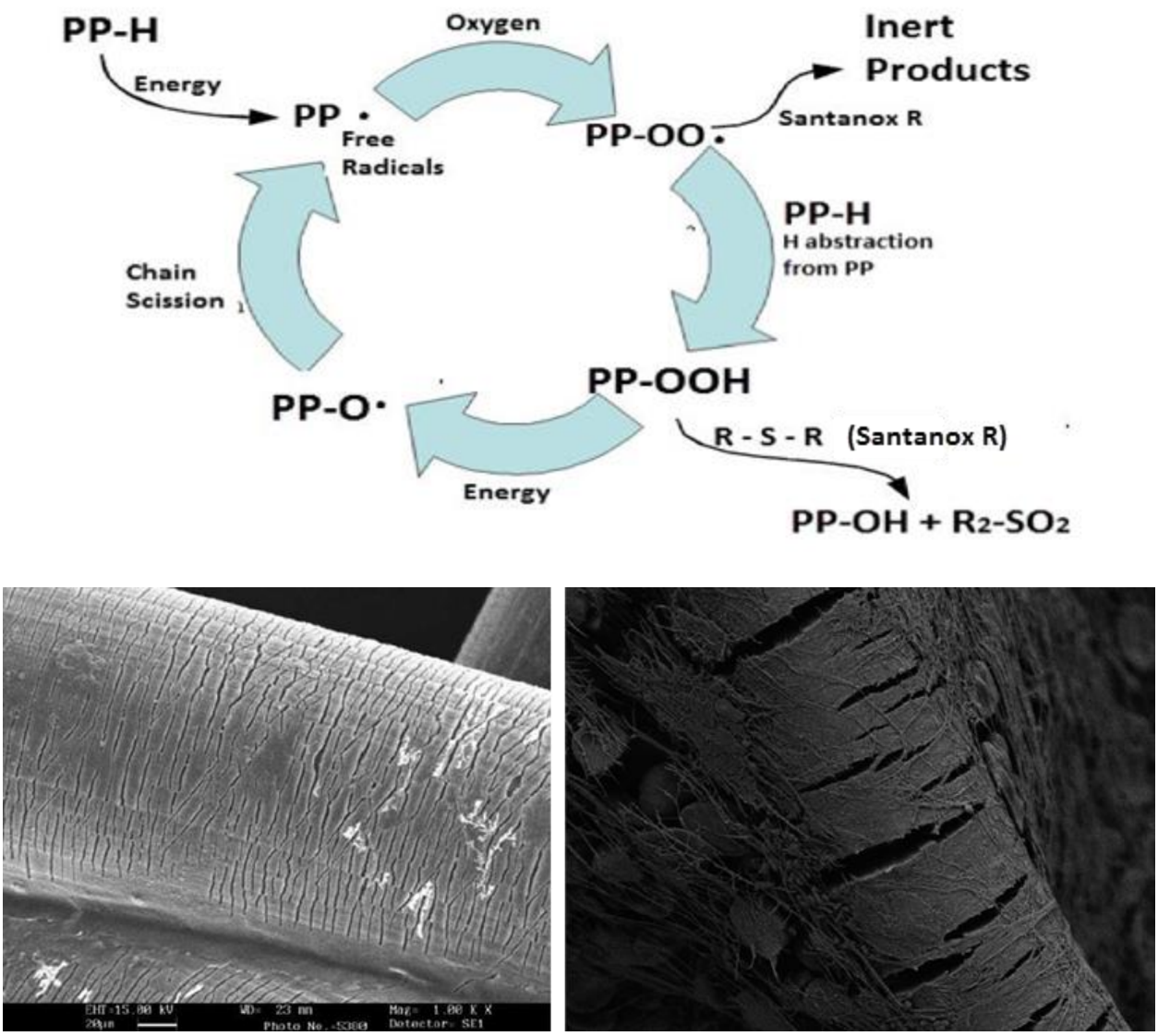


Figure 1. Scanning electron microscope (SEM) images of the surface of explanted meshes revealing severe surface degradation of the mesh fibers.[25]

VIII. SUMMARY AND CONCLUSIONS ON PP DEGRADATION SCIENCE

To summarize, from a plastic science perspective, I would not advise a medical device company to use PP for the permanently implantable mesh application because:

1) In order to fabricate a mesh, the PP polymer chains must be short;

2) PP mesh will rapidly lose its strength as the polymer chains disentangle when the mesh is placed under mechanical stress;

[25] "Post implantation Alterations of PP in the Human," Journal of Urology, 188, 27 – 32 (2012).

3) The PP is inherently oxidatively unstable compared with other plastics (because of the tertiary bonded hydrogen) forcing the addition of high levels of antioxidant stabilizers to be added to the PP to allow it to be stable enough to be fabricated into mesh without material degradation.

4) The antioxidants are depleted by migration from the mesh and by oxidation as they do their job to protect the PP against degradation.

5) Oxygenated liquids (e.g., blood, lipids and glycerides) present in body tissue extract antioxidants from the surface of the PP allowing rapid degradation and embrittlement of the surface of the mesh fibers.

IX. REVIEW OF RESEARCH ON PP MESH IMPLANTS

Polymers have been implanted in the body for several decades. All polymers degrade in the body and the basic science of degradation of different polymers in the body is known.[26] However, the rate at which a polymer degrades depends on the polymer's structure. For example, the rate of the oxidation reaction is about ten times faster when the hydrogen is bonded to a tertiary carbon (as is the case with PP) compared to a secondary carbon (as is the case with polyethylene). This is why PP degrades (by oxidation) much faster than other polymers, such as polyethylene.[27] PP meshes have also been used and studied for decades as well. Researchers at the University of Cincinnati College of Medicine found that unstabilized PP filaments begin to degrade after only a few days of implantation and that the mechanism of in vivo degradation is auto-oxidation similar to the degradation process that occurs during exposure of PP to air.[28] They found that the addition of appropriate antioxidants to the PP are required in order to stabilize the PP and increase the induction time for the start of the oxidative degradation process.

Professor Jimmy Mays at the University of Tennessee, recently (December 2015) published a paper in a peer reviewed journal (Biomaterials).[29] Professor Mays' research group showed that PP mesh implanted in the body undergoes rapid oxidative degradation leading to loss of filament strength and cracking. They conclude: "The overall degradation process of PP pelvic meshes may be summarized as follows. The implant causes increased activity by oxidative enzymes in the vicinity of the implant. This leads to an oxidative degradation process that is evidenced by appearance of hydroxyl and then carbonyl groups in the polypropylene, as observed by infrared spectra. There is accompanying degradation of the polypropylene molecular weight, and this process may be delayed, but not prevented, by the presence of antioxidants in the polypropylene. Antioxidants are preferentially consumed by the oxidizing species and finally the concentration falls below a level required to protect the polymer and oxidative degradation occurs. This degradation is accompanied by a decrease in mechanical properties (embrittlement, loss of mass, decreased melting temperature,

[26]"Handbook of Polymer Applications in Medicine and Medical Devices, 1st Edition; PDL Handbook Series. Editors: Modjarrad & Ebnesajjad , 386 pages, (2013); "Biomaterials, Medical Devices, and Combination Products: Biocompatibility Testing and Safety Assessment"; Taylor & Francis, CRC Press, 561 pages, 2015; Biodegradation of Surgical Polymers"; Journal of Material Science, 17, 1233 – 46 (1982); Comparison of PP and PET meshes for abdominal wall hernia repair: A chemical and morphological study"; Hernia, 9, 51–55 (2005).
[27] Biodegradation of Polypropylene and Polyethylene"; Indian Journal of Biotechnology, 7, 9 – 22 (2008).
[28] "Subcutaneous Implants of PP Filaments"; Journal of Biomedical Material Research, 10, 939 – 851 (1976).
[29]In Vivo Oxidative Degradation of Polypropylene Pelvic Mesh. Biomaterials (2015) Volume 73: 131-141.

reduced compliance) of the polypropylene. In particular, the surface and amorphous regions of the polypropylene are selectively degraded, resulting initially in cracks and, on longer exposure, fragmentation of the implant."[30] This is consistent with my opinion in this case.

X. ETHICON DEGRADATION RATE USING ACCELERATED LAB TESTING

Polymers are required to have a service life appropriate for their intended use. The term "service life" has a wide range of expectations. Some examples include exposure to high temperatures and aggressive solvents in automotive under-the-hood applications, long term service in elevated temperature environments such as electronic circuit boards, the ability of plastic pipes to withstand high pressure for decades while being exposed to chlorinated water, and the ability to withstand weather extremes in residential siding. In all of these examples, design engineers require information on polymer properties as a function of service time in order to create viable parts that meet the service expectation. In medical applications selecting the right material to manufacture implants is even more critical because failure can be life-threatening. Responsible medical device companies use accelerated aging testing to predict the estimated time to failure of the product. It can create a so-called red flag; if accelerated lab testing predicts a failure time that is shorter than the amount of time that the medical device can be present in the body, a responsible manufacturer should conduct additional, lengthier tests to confirm that the material is (or is not) stable enough to remain in the body for the length of time required. Many approaches have been utilized to accelerate natural polymer aging and gain necessary engineering data in a reasonable time frame.

The essence of any accelerated aging methodology begins with an understanding of the stresses applied to the polymer during service and how those stresses may affect aging properties. Some typical polymeric stressors include thermal, oxidative, chemical, and physical stresses. Polymer degradation can be modeled as a series of kinetically controlled chemical reactions. Generally, successful accelerated aging methodology intensifies the primary stressors in a controlled manner in order to increase the rate of the overall rate-controlling reaction(s). As analytical methodologies have become ever more sensitive it has become possible to detect the chemical changes which are precursors to polymer degradation, allowing rapid determination of degradation kinetics on very small samples. Once the degradation kinetics are measured, the kinetic data can be used to create kinetic models which allow predictions of degradation rates at normal use temperatures.

The main stressors for aging and degradation of implanted meshes include oxidation and mechanical load. Since the job of the mesh is to support weakened human tissue, it is under constant stress. By performing accelerated testing to measure the rate of oxidation while the sample is not under mechanical stress, we realize that the data is heavily biased to yield data that would predict unrealistically long life. However, it is my expert opinion that the data is still useful, at least for sample to sample comparison, to gain information regarding mesh oxidation resistance variability.

The accelerated method selected to compare the oxidation resistance of the Ethicon meshes is ASTM D3895 "Oxidative Induction Time using Differentia Scanning Calorimetry (DSC)" or OIT. This is a standard test method that is widely followed and accepted in my field. I utilize this

[30] Degradation of polypropylene in vivo: A microscopic analysis of meshes explanted from patients"; Journal Biomed Mater Res Part B: Applied Biomaterials 91B: 1 - 12, (2015).

testing procedure extensively in my profession. The method is used to determine whether polyolefin resins such as polyethylene and PP are appropriately stabilized. The method involves placing a small (~10 milligrams) fiber of the mesh inside a very sensitive instrument called a differential scanning calorimeter (DSC). The instrument detects when chemical oxidation occurs because chemical oxidation gives off heat. The mesh sample is heated to 200°C under pure nitrogen and then the atmosphere inside the instrument is changed to oxygen. The OIT for the sample is the time it takes before an exotherm to be detected. As long as the antioxidants are present in the sample protecting the PP against oxidation, no exotherm is detected. However, the detection of an exotherm means that the antioxidants have been depleted and the PP is undergoing rapid oxidative degradation. A graph showing the output data from an OIT test of one of the Ethicon mesh samples is shown in Figure 2. In the Ethicon mesh sample shown in Figure 2, notice that a slight exotherm is detected several minutes before the main catastrophic OIT exotherm. The first point of exotherm detection is the incipient surface oxidation temperature (ISOT), which derives from the OIT test. The OIT test follows ASTM D3895. The ASTM D3895 test has been relied on for many years for polyethylene and polypropylene plastics. The test is used by companies when designing a product to make sure there is an appropriate level of stabilizer in a product so it will not fail in the end use.

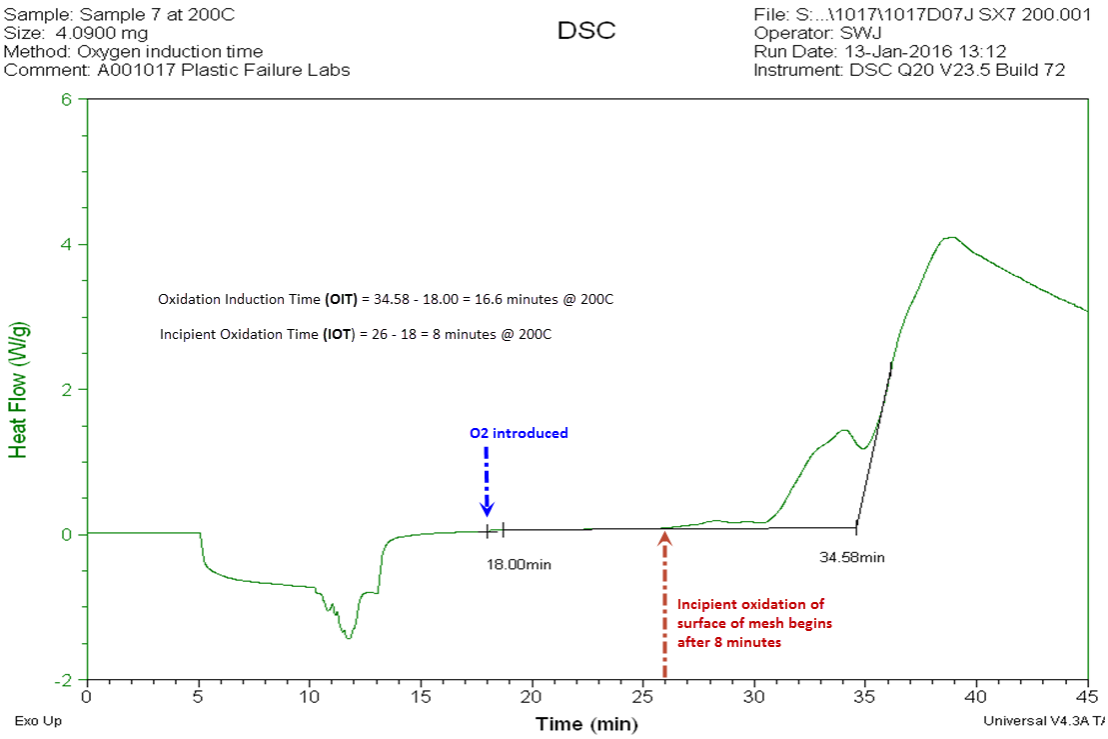


Figure 2. OIT test result on Ethicon mesh Gynecare TVT 810041BL, Lot 3405405. After 8 minutes of exposure to oxygen, incipient oxidation/degradation begins. After 16.6 minutes catastrophic oxidation takes place.

Ten different samples of Ethicon meshes were received from Counsel using an appropriate Chain of Custody. The OIT and ISOT of each mesh sample were measured. Significant variability was

found between the oxidative resistances of the ten meshes. As mentioned previously, the oxidative process begins rapidly on the mesh surface causing embrittlement due to degradation.

It should be pointed out that the OIT testing was performed in an environment where there is no mechanical stress[31] and no loss of antioxidant occurred due to migration from the surface into a liquid environment (like inside the body). Therefore the OIT data is a best case situation because the only mechanism for loss of antioxidant during the OIT tests is chemical reaction; i.e., loss by migration into body fluids is not taken into account. We know from the literature that migration of the antioxidant from the plastic into the surrounding medium is significant.[32] A study of polyolefin resins stabilized with Santonox R (antioxidant present in the PP at issue) found that, in oxygenated water, the Santanox R migrates from the surface of the plastic into the water. The study states: "The loss of Santonox R in samples exposed to water saturated with air was faster than for the samples exposed to oxygen-free water. This was due to increased mass transport of the antioxidant from the polymer phase boundary to the water phase when oxygen was present.... Results obtained by liquid chromatography of extracts confirmed that the gradual decrease in OIT with increasing ageing time was due to migration of antioxidant to the surrounding medium."[33]

XI. CORRELATION OF THE LEVEL OF ANTIOXIDANTS IN MESH SAMPLES WITH OIT

The antioxidants present in the 10 meshes were then extracted from the mesh using methylene chloride solvent. The ten samples were all extracted at the same time for 72 hours by sonication of approximately the same weight of mesh sample in approximately the same weight of methylene chloride solvent (containing an internal standard). The ten extracts were then analyzed using GC-MS to identify and quantify the relative amount of Santanox R antioxidant present in the mesh samples. The variation in the amount of Santanox R present in the ten mesh samples was significant and correlated with the variation in the OIT of the same mesh samples.

XII. ETHICON DOCUMENTS SUPPORT MESH DEGRADATION

I have reviewed internal Ethicon documents regarding outcomes associated with the implantation of Prolene sutures in canine explant studies.[34] These internal Ethicon studies revealed cracking and deformation of the Prolene sutures in response to oxidation and embrittlement. I have also reviewed internal Ethicon documents regarding Ethicon human

[31] "Standard Practice for Heat Aging of Plastics without Load," ASTM Report D3045, West Conshohocken, PA, ASTM.
[32] "Loss of stability by migration and chemical reaction of Santonox R..."; Polymer Degradation and Stability 91, 1071-1078 (2006).
[33] "Loss of stability by migration and chemical reaction of Santonox R..."; Polymer Degradation and Stability 91, 1071-1078 (2006).
[34] Eth.Mesh.12729337 ("Five Year Results from Ten Year Prolene Study"); Eth.Mesh.07690752 ("Seven Year Data for Ten Year Prolene Study"); Eth.Mesh.05453719; Eth.Mesh.09557798; Eth.Mesh.113361184 (Protocol of 10 Year In Vivo Dog Study); Eth.Mesh.11336071 ("2 Year Dog Study Interim Report"); Eth.Mesh.11336165 (5 Year Data): Eth.Mesh.09888187 (7 Year Data); Eth.Mesh.11336181 ("Interim Report on the Physical Testing").

explant studies involving Prolene sutures from the 1980s which show Prolene's vulnerability to oxidative changes.[35] The results of these studies are consistent with my opinions in this case.

XIII. EXPERT OPINION

It is my expert opinion within a reasonable degree of scientific certainty that Ethicon knew or should have known that PP was not an appropriate material for use in permanent medical implants of transvaginal mesh. My opinion is independently supported in the scientific literature, by my peers and in my field of expertise. The testing I performed using written ASTM standards and followed well-established methodologies that have existed in my field for decades. The testing and analyses that I have performed as part of my work in this case provides further support for my opinions and was accessible and available to Ethicon when they were designing their PP mesh devices for SUI and POP treatment. Ethicon could have performed this testing when designing these devices. Had Ethicon performed this testing as a reasonable medical device manufacturer, it would have detected a so-called "red flag" alerting it to both the degradation of the PP mesh, the reduced life expectancy of the product, and the leaching / use of the antioxidant package in the PP resin. Ethicon then should have, as a reasonable manufacturer, performed additional tests to determine whether the PP would withstand permanent implantation in the body. Ethicon's failure to do so deviates from the standards of a reasonable company and in this case jeopardized the health of the women receiving their products. This opinion is based upon my decades of experience working with plastics, my testing of Ethicon meshes, my review and knowledge of the science and literature in my field of expertise and my review of the documents listed in Section XVI.

XIV. COMPENSATION

I received a $3500 retainer check on October 19th 2015 as a deposit toward my expert services in this matter. I am being paid $375/hour for my expert services performed from my office. I will be paid $550 for oral testimony under oath in this matter.

XV. FACTS AND DATA CONSIDERED

In addition to the materials cited in this report, I have also considered the materials listed in Exhibit B in forming my opinions in this case.

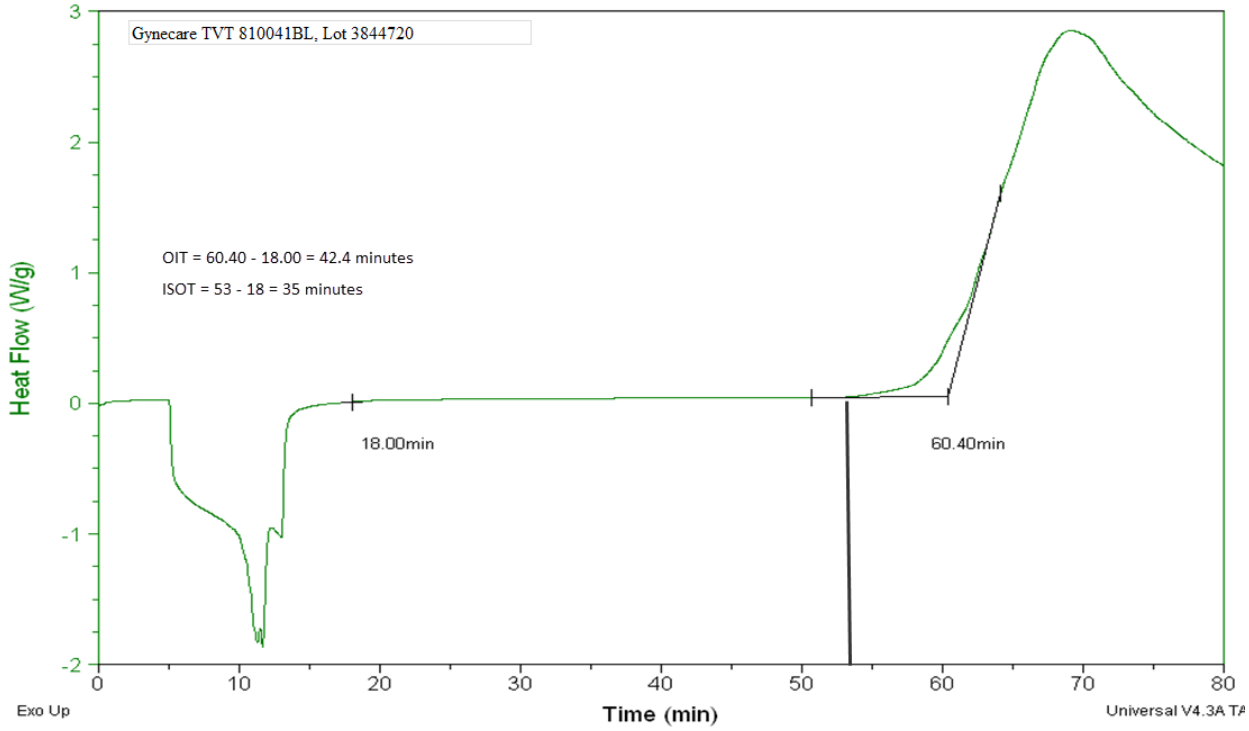
XVI. APPENDIX

[35] Eth.Mesh.12831391 ("IR Microscopy of Explanted Prolene Received from Prof. R. Guidoin").

Sample: Sample 1 at 200C
Size: 5.8900 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs

DSC

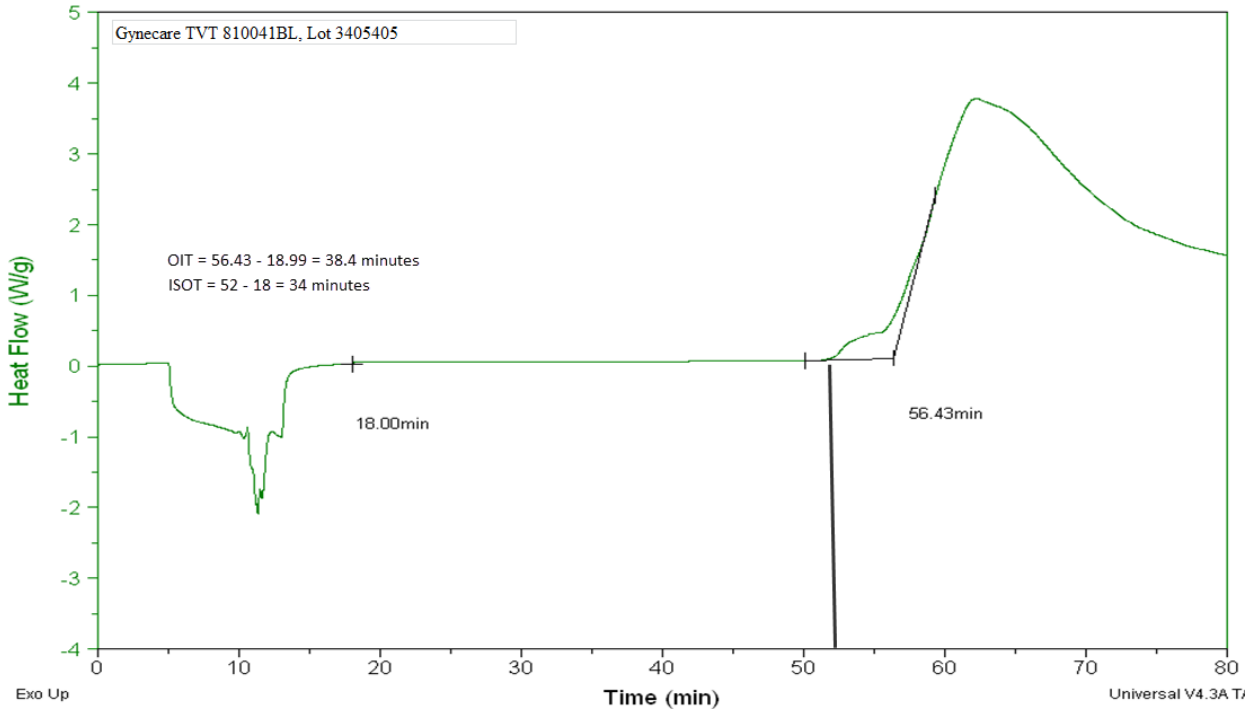
File: S:...\1017\1017D2005RMSX1.001
Operator: SWJ
Run Date: 19-Jan-2016 10:24
Instrument: DSC Q20 V23.5 Build 72

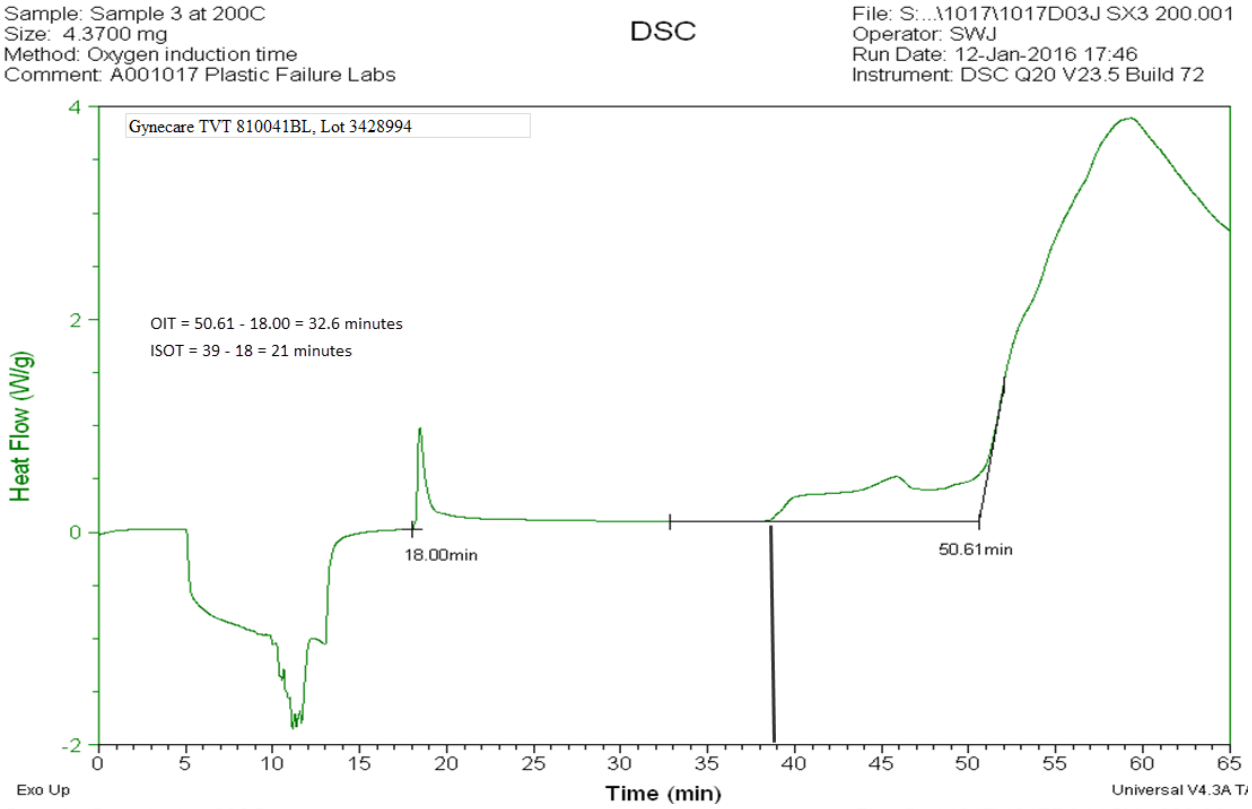


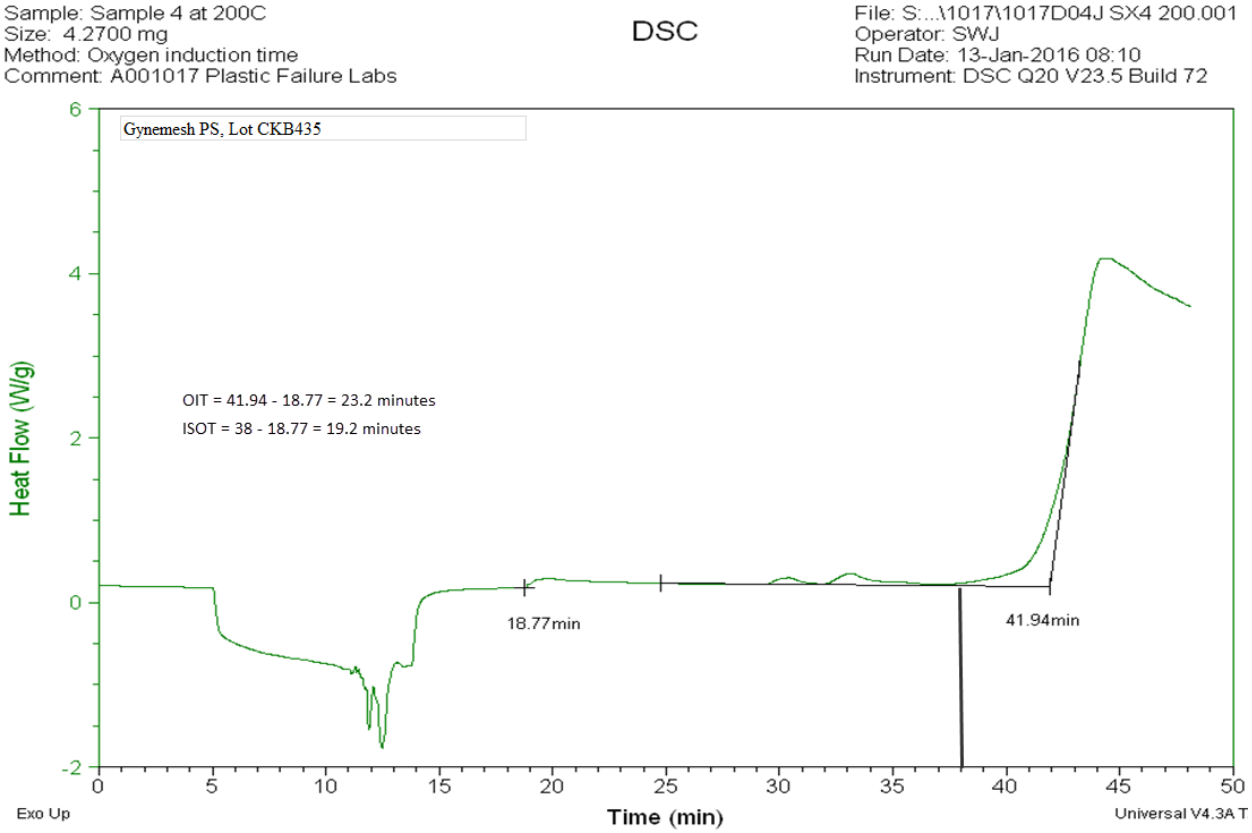
Sample: Sample 2 at 200C
Size: 4.6400 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs

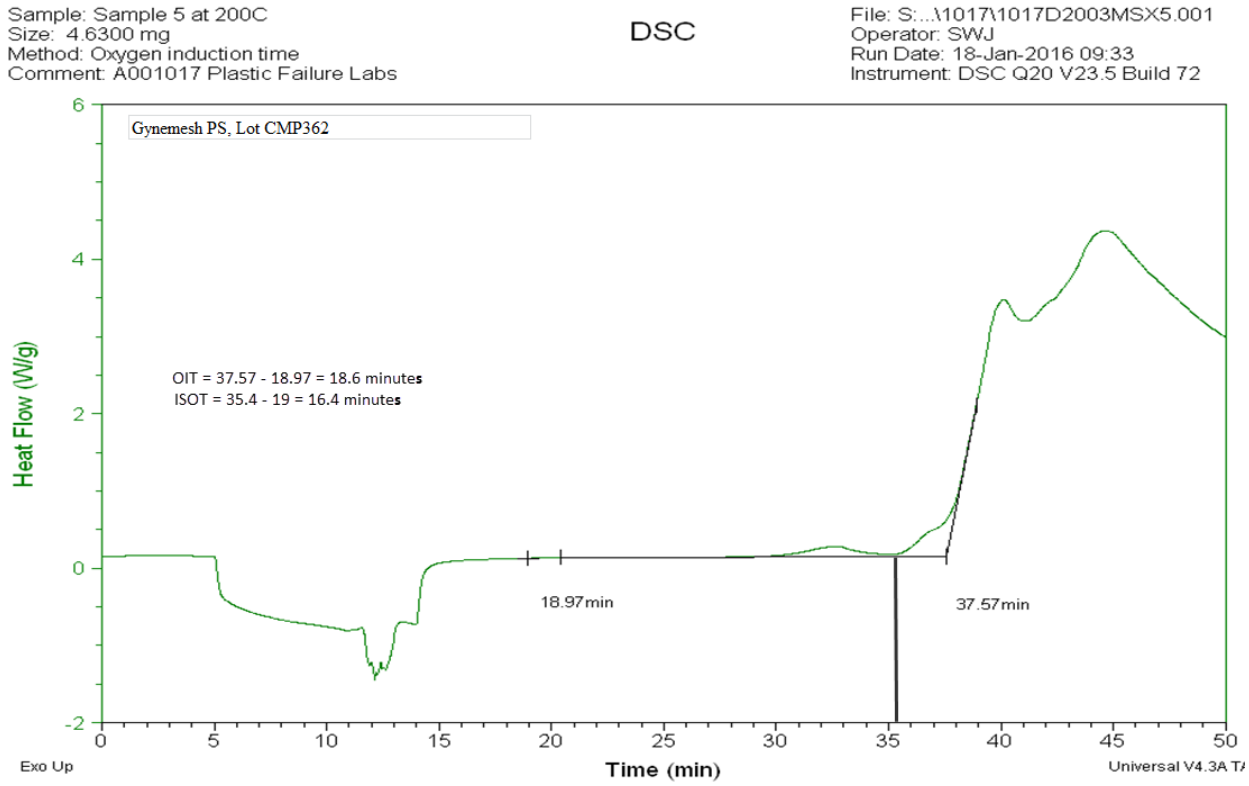
DSC

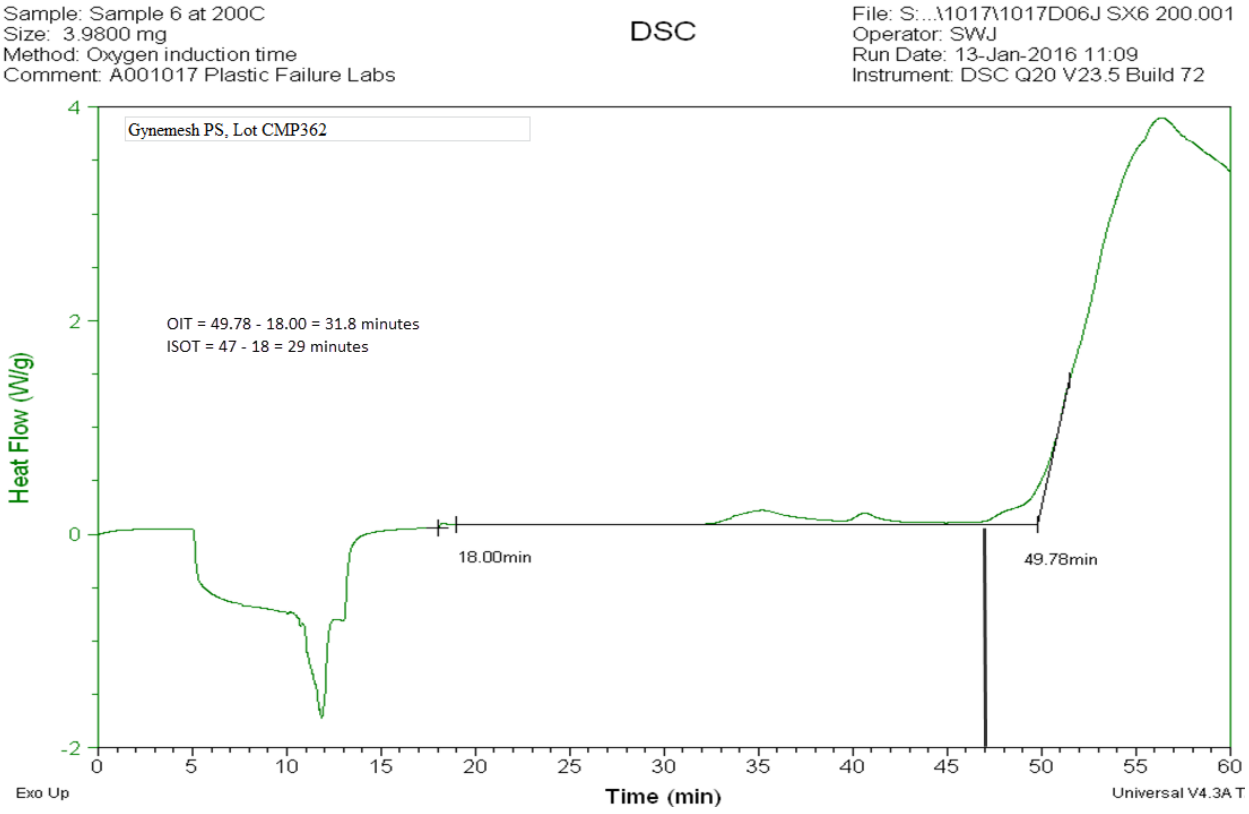
File: S:...\1017\1017D2001RMSX2.001
Operator: SWJ
Run Date: 19-Jan-2016 12:13
Instrument: DSC Q20 V23.5 Build 72




Sample: Sample 3 at 200C
Size: 4.3700 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs
DSC
File: S:...\1017\1017D03J SX3 200.001
Operator: SWJ
Run Date: 12-Jan-2016 17:46
Instrument: DSC Q20 V23.5 Build 72
Gynecare TVT 810041BL, Lot 3428994
OIT = 50.61 - 18.00 = 32.6 minutes
ISOT = 39 - 18 = 21 minutes
18.00min
50.61min
Heat Flow (W/g)
Time (min)
Exo Up
Universal V4.3A T


Sample: Sample 4 at 200C
Size: 4.2700 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs
DSC
File: S:...\1017\1017D04J SX4 200.001
Operator: SWJ
Run Date: 13-Jan-2016 08:10
Instrument: DSC Q20 V23.5 Build 72
Gynemesh PS, Lot CKB435
OIT = 41.94 - 18.77 = 23.2 minutes
ISOT = 38 - 18.77 = 19.2 minutes
18.77min
41.94min
Heat Flow (W/g)
Time (min)
Exo Up
Universal V4.3A T

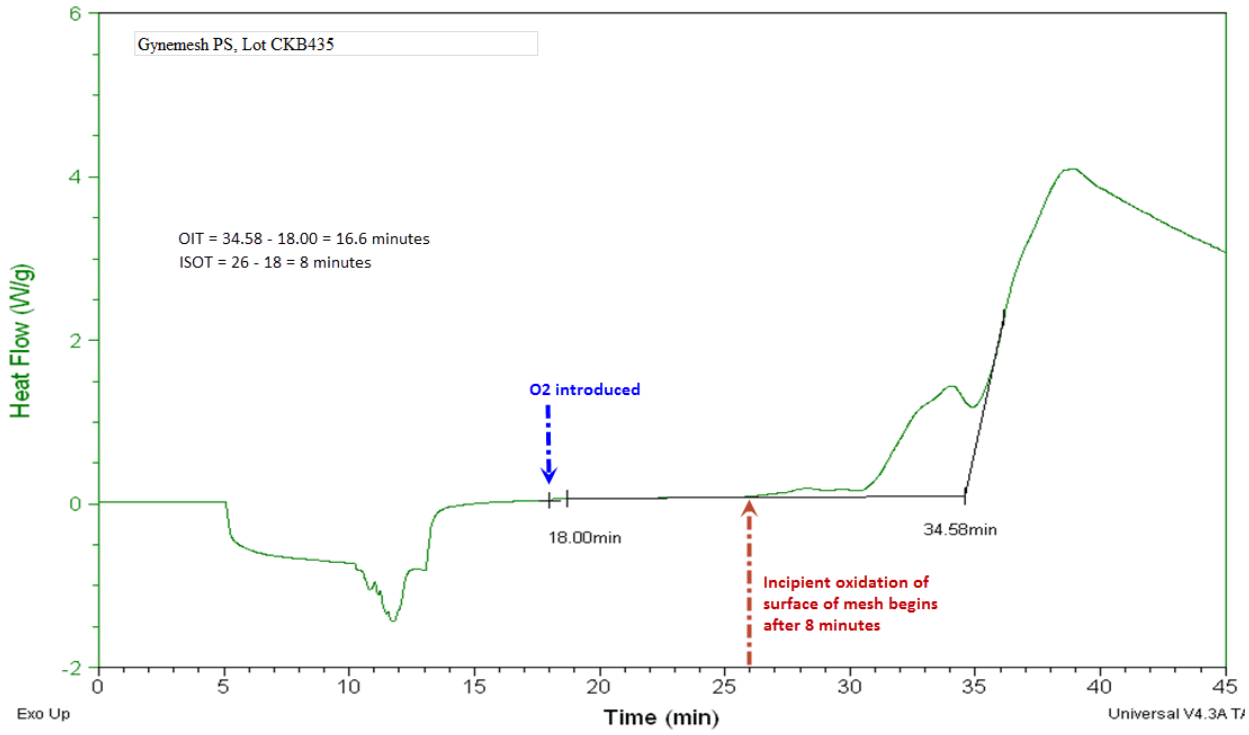

Sample: Sample 5 at 200C
Size: 4.6300 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs
DSC
File: S:...\1017\1017D2003MSX5.001
Operator: SWJ
Run Date: 18-Jan-2016 09:33
Instrument: DSC Q20 V23.5 Build 72
Gynemesh PS, Lot CMP362
OIT = 37.57 - 18.97 = 18.6 minutes
ISOT = 35.4 - 19 = 16.4 minutes
18.97min
37.57min
Heat Flow (W/g)
Time (min)
Exo Up
Universal V4.3A TA


Sample: Sample 6 at 200C
Size: 3.9800 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs
DSC
File: S:...\1017\1017D06J SX6 200.001
Operator: SWJ
Run Date: 13-Jan-2016 11:09
Instrument: DSC Q20 V23.5 Build 72
Gynemesh PS, Lot CMP362
OIT = 49.78 - 18.00 = 31.8 minutes
ISOT = 47 - 18 = 29 minutes
18.00min
49.78min
Heat Flow (W/g)
Time (min)
Exo Up
Universal V4.3A T

Sample: Sample 7 at 200C
Size: 4.0900 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs

DSC

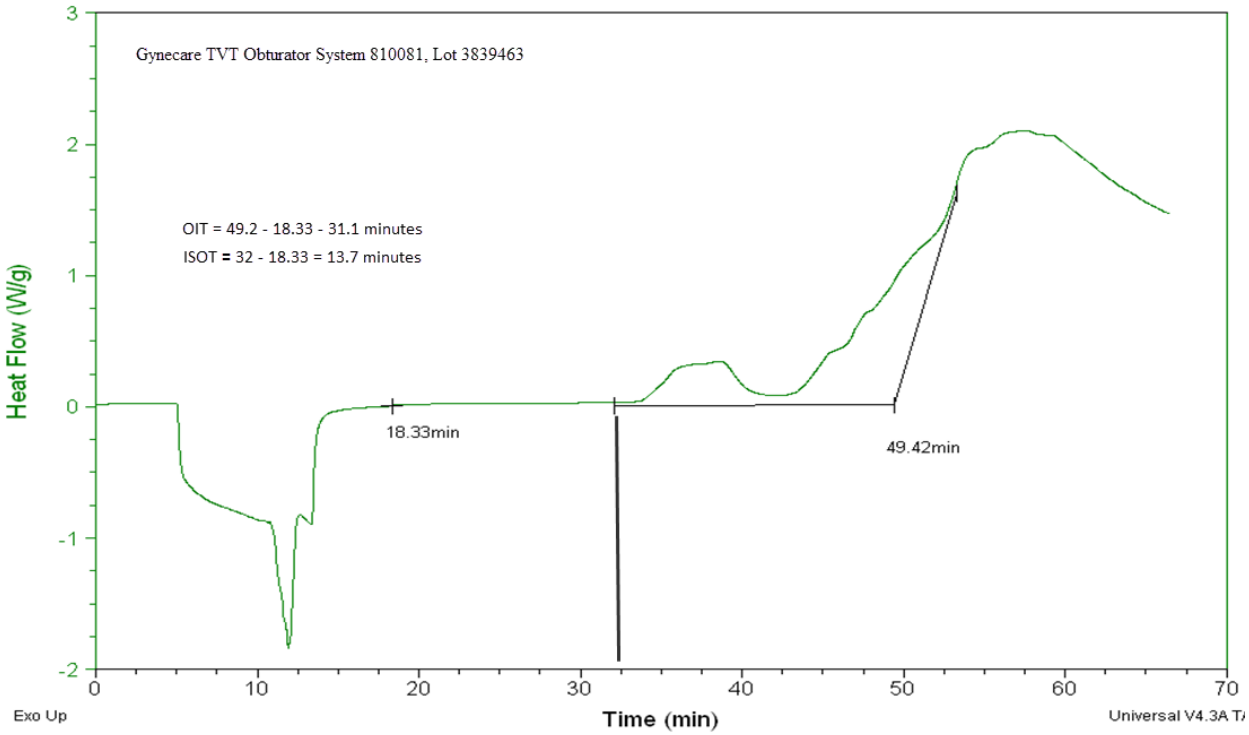
File: S:...\1017\1017D07J SX7 200.001
Operator: SWJ
Run Date: 13-Jan-2016 13:12
Instrument: DSC Q20 V23.5 Build 72

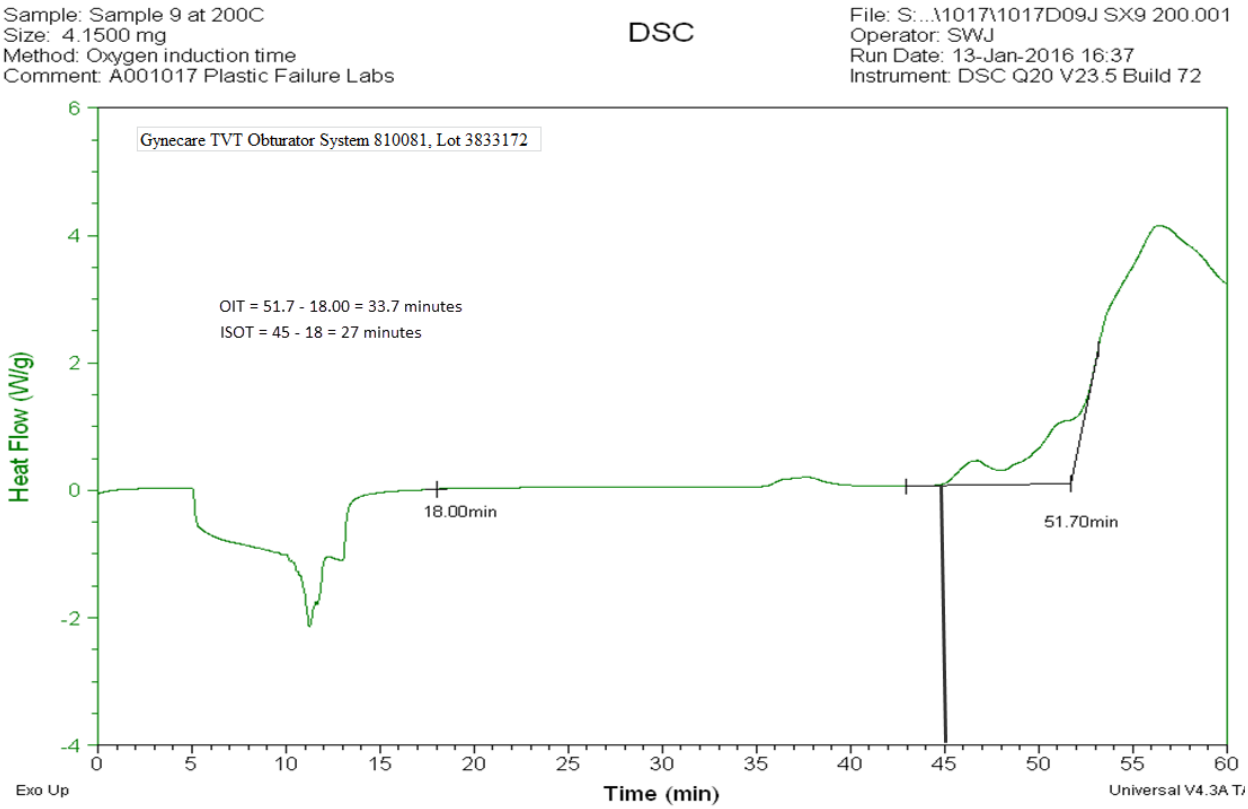


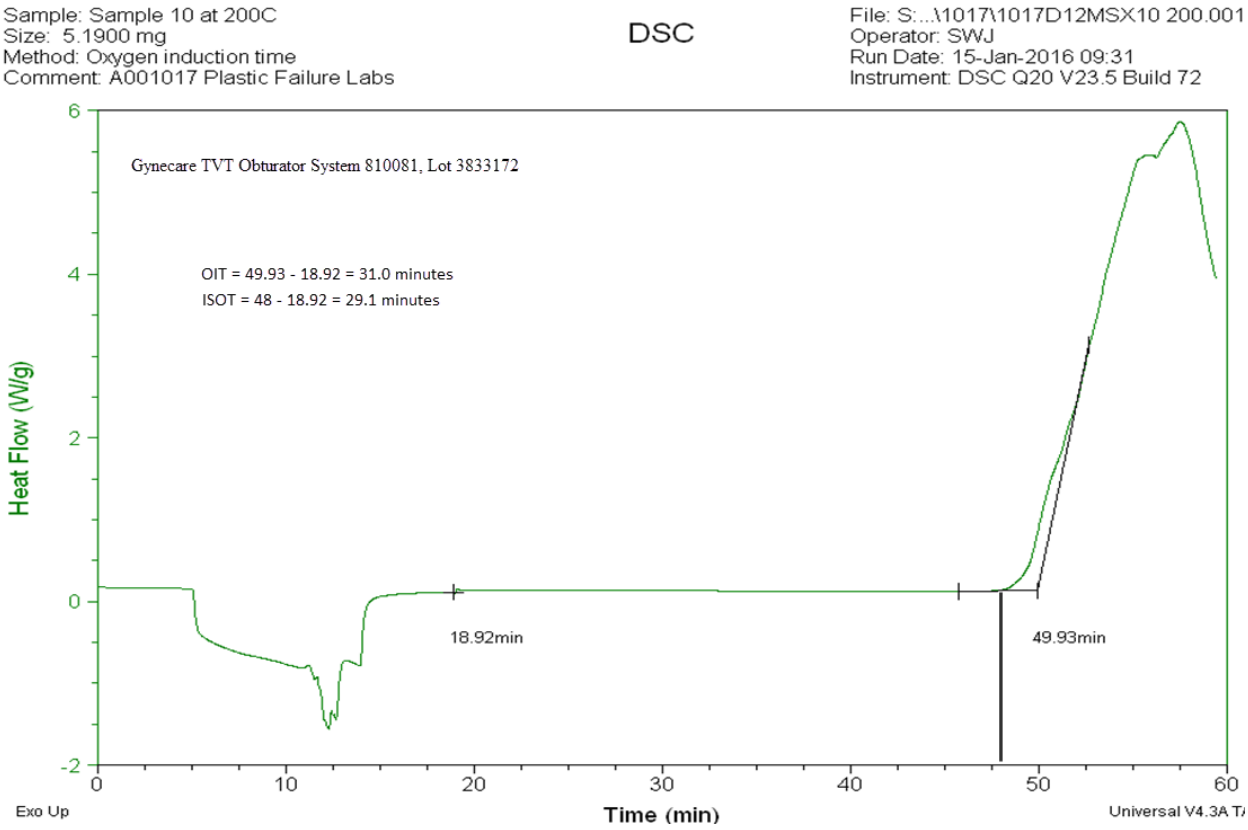
Sample: Sample 8 at 200C
Size: 6.7100 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs

DSC

File: S:...\1017\1017D312MSX8.001
Operator: MMR
Run Date: 22-Jan-2016 13:21
Instrument: DSC Q20 V23.5 Build 72




Sample: Sample 9 at 200C
Size: 4.1500 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs
DSC
File: S:...\1017\1017D09J SX9 200.001
Operator: SWJ
Run Date: 13-Jan-2016 16:37
Instrument: DSC Q20 V23.5 Build 72
Gynecare TVT Obturator System 810081, Lot 3833172
OIT = 51.7 - 18.00 = 33.7 minutes
ISOT = 45 - 18 = 27 minutes
18.00min
51.70min
Heat Flow (W/g)
Time (min)
Exo Up
Universal V4.3A T


Sample: Sample 10 at 200C
Size: 5.1900 mg
Method: Oxygen induction time
Comment: A001017 Plastic Failure Labs
DSC
File: S:...\1017\1017D12MSX10 200.001
Operator: SWJ
Run Date: 15-Jan-2016 09:31
Instrument: DSC Q20 V23.5 Build 72
Gynecare TVT Obturator System 810081, Lot 3833172
OIT = 49.93 - 18.92 = 31.0 minutes
ISOT = 48 - 18.92 = 29.1 minutes
18.92min
49.93min
Heat Flow (W/g)
Time (min)
Exo Up
Universal V4.3A T

XVII. LISTING OF CASES IN WHICH TESTIMONY HAS BEEN GIVEN THE LAST FOUR YEARS

Fabara v GoFit

Boiko v Kikkerland

Jones v Heil

Patients v AMS

Esplanade v Fifth & Continental

Rubitsky v BMW

Yucatan Foods v Berry Plastics

Sincerely,

Duane Priddy, Ph.D.